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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/646,109 | 08/22/2003 | Heinz Kontschieder | WP 21241 US | 8428 |

7590 12/08/2006

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| EXAMINER | |
|---|---|
| VATHYAM, SUREKHA | |
| **ART UNIT** | **PAPER NUMBER** |
| 1753 | |

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/646,109 | KONTSCHIEDER ET AL. | |
| | Examiner | Art Unit | |
| | Surekha Vathyam | 1753 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 August 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/25/03, 1/10/05, 05/25/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Priority*

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. Receipt is acknowledged of papers filed under 35 U.S.C. 119 (a)-(d) based on an application filed in Austria on 08/23/02. Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath, declaration or application data sheet does not acknowledge the filing of the appropriate foreign application. The oath makes reference to A 2167/2002, which is different from the submitted certified copy corresponding to A 1267/2002. A new oath, declaration or application data sheet is required in the body of which the present application should be identified by application number and filing date.

### *Drawings*

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "2" in Fig. 2 (page 7, last paragraph, 2nd line). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of

an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Objections*

4. Claim 4 is objected to because of the following informalities: line 2 of claim 2 has the phrase "measurement the electrodes". It is unclear what this term means. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 – 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1 and 10 recite the limitation "the flow measuring cell" in line 1 of claim 1 and line 2 of claim 10. There is insufficient antecedent basis for this limitation in the claims.

8. Claim 4 recites the limitation "systems for continuous measurement" on lines 1 – 2. There is insufficient antecedent basis for this limitation in the claims.

9. Dependent method claims 12 and 13 each depend on independent apparatus claim 1. Single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph. *IPXL Holdings v. Amazon.com, Inc.*, 430 F.2d 1377, 1384, 77 USPQ2d 1140, 1145 (Fed. Cir. 2005); *Ex parte Lyell,* 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990).

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1 – 2 and 7 – 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pace et al. (US 5,284,568) in view of Beaty et al. (US 6,645,368).

Regarding claim 1, Pace ('568) discloses a device (see Fig. 1). None of claims 1 – 9 and 12 – 13 positively recite any further structural elements beyond simply a device. While various intended operations and elements are discussed in the claims, there is no requirement that the device include any additional elements. The applicant is reminded of the following decisions:

"[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham,* 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). "[T]he manner or method in which such machine is to be utilized is not germane to the issue of patentability of the machine itself." *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967).

While it is understood that no specific structural elements are required nonetheless regarding claim 1, Pace ('568) discloses a device (see Fig. 1) for monitoring a medical microsample (column 1, lines 12 – 18) in the flow measuring cell

of an analyzer (column 2, lines 15 – 38) with regard to position (column 3, line 61 – 68) and the absence of bubbles (column 4, line 3 – 7) by means of an alternating voltage applied to the measuring cell (column 5, lines 5 – 12), said measuring cell being provided with a multitude of electrode systems (see Fig. 6), which are placed one behind the other and comprise a number of single electrodes (52) each, for measuring a substance contained in the microsample (column 3, lines 61 – 68) by means of a measurement voltage (column 5, lines 5 – 12 and column 6, lines 29 – 41), wherein both the alternating voltage and the measurement voltage are directly applied to the single electrodes of the respective electrode system (see Fig. 6), and wherein the measured AC component or the measured impedance provides a measure for the position of the microsample and the absence of bubbles (column 6, lines 42 – 47).

Pace ('568) does not explicitly disclose the measurement voltage to be essentially a DC voltage and Pace ('568) does not explicitly disclose the simultaneous application of the alternating and measurement voltage though Fig. 6 clearly shows this to be the case.

Beaty ('368) teaches a measurement voltage that is a DC voltage (column 10, line 49 – column 11, line 16) and simultaneous application of an alternating and a measurement voltage (column 12, lines 62 – 65).

It would have been obvious to one of ordinary skill in the art to have modified the device of Pace ('568) to include a DC measurement voltage and simultaneous application of alternating and measurement voltages as taught by Beaty ('368) because as Beaty ('368) explains the measurement voltage enables concentration determination

of a medically significant component of a biological fluid (column 4, lines 14 – 21) while the AC impedance permits monitoring the position of a sample and any other interferrent present (column 7, lines 35 – 44), such as an air bubble.

Regarding claim 2, Pace ('568) discloses the device wherein the electrode system includes a working electrode and a reference electrode (column 3, lines 61 – 68), both electrodes serving as electrical contacts (column 4, lines 8 – 18) and inherently capable of measuring impedance.

Regarding claim 7, Pace ('568) discloses the device wherein electronic circuitry (96) is provided for producing the voltages to be applied to the single electrodes (52, 54 and 56) (column 5, lines 5 – 12).

Pace ('568) does not explicitly disclose a summation point.

Beaty ('368) teaches a circuit with a summation point at which alternating voltage for the purpose of monitoring medical microsample with regard to position and absence of bubbles is superposed on the DC voltage serving as a measuring voltage (column 9, lines 6 –7).

It would have been obvious to one of ordinary skill in the art to have modified the device of Pace ('568) to include the summation point as taught by Beaty ('368) because it enables the discrete determination of concentration of components in the medical sample while also allowing for the monitoring the presence of sample or bubbles as taught by Beaty ('368) (column 9, lines 8 – 17).

Regarding claim 8, Beaty ('368) teaches a summation point is connected with the inverting input terminal of an operational amplifier (see Figs 2 and 3 and column 11, line 32 – column 12, line 11).

Regarding claim 9, Pace ('568) discloses the device wherein the electrode system is provided with a device for measuring impedance (column 6, lines 43 – 47).

Pace ('568) does not explicitly disclose a circuit for superposing an alternating voltage on a DC voltage.

Beaty ('368) teaches the superposition of alternating voltage on a DC voltage (column 9, lines 6 –7).

It would have been obvious to one of ordinary skill in the art to have modified the device of Pace ('568) to include a circuit for superposition of alternating voltage on DC voltage as taught by Beaty ('368) because it enables the discrete determination of concentration of components in the medical sample while also allowing for the monitoring the presence of sample or bubbles as taught by Beaty ('368) (column 9, lines 8 – 17).

Regarding claim 10, Pace ('568) discloses a method for monitoring a medical microsample (column 1, lines 12 – 18) with regard to position (column 3, line 61 – 68) and absence of bubbles (column 4, line 3 – 7), which is introduced into the flow measuring cell of an analyzer (column 2, lines 15 – 38) and passes a multitude of

electrode systems (see Fig. 6), each comprising a number of single electrodes (52) for measuring a substance contained in the microsample (column 3, lines 61 – 68) by means of a measurement voltage (column 5, lines 5 – 12 and column 6, lines 29 – 41), wherein an alternating voltage is coupled in via two single electrodes (56 and 54) of at least one electrode system, and wherein the AC component or impedance measured is used as a measure for the sample position and absence of bubbles of the microsample in the area of the at least one electrode system (column 6, lines 42 – 47).

Pace ('568) does not explicitly disclose the measurement voltage to be essentially a DC voltage.

Beaty ('368) teaches a measurement voltage that is a DC voltage (column 10, line 49 – column 11, line 16).

It would have been obvious to one of ordinary skill in the art to have modified the method of Pace ('568) to include a DC measurement voltage as taught by Beaty ('368) because as Beaty ('368) explains it enables concentration determination of a medically significant component of a biological fluid (column 4, lines 14 – 21) while the AC impedance permits monitoring the position of a sample and any other interferrent present (column 7, lines 35 – 44), such as an air bubble.

Regarding claim 11, Beaty ('368) teaches a method wherein the measurement voltage and alternating voltage are coupled in simultaneously (column 12, lines 62 – 65).

Regarding claim 12, while it is not clear what exactly is being claimed due to a method claim depending on an apparatus claim as discussed previously, nonetheless Beaty ('368) teaches a method wherein a predetermined value for impedance when obtained, indicates that the microsample is positioned precisely in the area of the respective electrode system (column 10, lines 13 – 25).

Regarding claim 13, while it is not clear what exactly is being claimed due to a method claim depending on an apparatus claim as discussed previously, nonetheless Pace ('568) discloses the absence of bubbles of microsample are determined in the area of each electrode system (column 4, lines 3 – 7) and Beaty ('368) teaches sample position is determined in the area of each electrode system (column 8, lines 40 – 42).

14. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pace et al. (US 5,284,568) in view of Beaty et al. (US 6,645,368) as applied to claim 1 above, and further in view of Matson (US 4,511,659).

Regarding claim 3, Pace ('568) discloses the device wherein the electrode system includes a working electrode and a reference electrode (column 3, lines 61 – 68) with electrical contacts (column 4, lines 8 – 18) inherently capable of measuring impedance.

Pace ('568) does not explicitly disclose a counter electrode although sensing elements (52) could inherently function as such (column 3, lines 61 – 68).

Matson ('659) teaches a counter electrode (36a through 36f; see Fig. 1 and column 4, line 67 – column 5, line 5).

It would have been obvious to one skilled in the art to have modified the device of Pace ('568) to include a counter electrode as taught by Mason ('659) because it is well-known in the art as evidenced by the teaching of Mason ('659) and it provides an electrochemical flow cell which is capable of rapidly and reliably detecting substances in biological samples (column 1, lines 53 – 57) as taught by Mason ('659).

Regarding claim 4, while it is unclear what is being claimed, as discussed above, the claims have been considered with regard to the prior art to the extent possible. Mason ('659) teaches working electrode in sequence with reference electrode and counter electrode (see Fig. 1 and column 5, lines 37 – 40).

15. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pace et al. (US 5,284,568) in view of Beaty et al. (US 6,645,368) and Matson (US 4,511,659) as applied to claim 3 above, and further in view of Taniike et al. (US 7,022,218).

Regarding claim 5, Matson ('659) teaches counter electrodes placed both in front of and behind the working electrode in flow direction of the microsample (see Fig. 1 and column 5, lines 37 – 40) but does not explicitly teach the counter-electrodes being electrically short-circuited.

Taniike ('218) teaches counter-electrodes being electrically short-circuited (column 5, lines 17 – 20).

It would have been obvious to one of ordinary skill in the art to have modified the device of Pace ('568) in view of Beaty ('368) and Matson ('659) to include the short-circuiting of counter electrodes as taught by Taniike ('218) because it enables them to function as a counter electrode and facilitate the measurement of the glucose in the sample as taught by Taniike ('218) (column 9, lines 6 – 10).

Regarding claim 6, Taniike ('218) teaches a counter electrode and working electrode positioned opposite each other in a measuring cell (column 5, lines 41 – 46).

***Conclusion***

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kassel (US 3,811,841) discloses flow cell with bubble detection using conductivity.

Bodai et al. (US 4,929,426) discloses sample position detector.

Marsoner et al. (US 5,130,009) discloses sensor device with conductivity and impedance measurements.

Tanaka et al. (US 5,763,795) disclose bubble detection using impedance measurements.

Bhullar et al. (US 6,447,657) discloses interdigitated multi-electrode biosensor.

Künnecke (US 6,544,393) addresses bubble formation at electrodes that distort signal.

Taagaard et al. (US 6,723,216) discloses a method and apparatus for detection of a bubble in a liquid.

Kermani et al. (US 6,872,299) discloses detection of presence of a sample.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Surekha Vathyam whose telephone number is 571-272-2682. The examiner can normally be reached on 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SV
December 5, 2006

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